MAY 2 2 2014

K140027

510(k) Summary

The following section is included as required by the Safe Medical Devices Act (SMDA) of 1990 and 21CFR 807.92

Company name	Materialise N.V.
Establishment registration number	3003998208
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City	Leuven
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Principal Contact person	Oliver Clemens
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Additional contact person	Wim Claassen
Contact title	Product Manager
Contact e-mail address	Wim.Claassen@materialise.be

Submission date

The date of the Traditional 510(k) submission is January 2nd 2014

Submission information

Trade Name	*Zimmer*® Patient Specific Instruments *Zimmer*® Patient Specific Instruments Planner
Common Name	Knee prosthesis
Classification Name	Knee joint patellofemorotibial polymer /metal /polymer semi-constrained cemented prosthesis
Primary product code	JWH (21 CFR 888.3560)
Subsequent product codes	MBH, OOG and OIY

Predicate Devices

The predicate device to which substantial equivalence is claimed to:

Trade or property or model name	*Zimmer*® Patient Specific Instruments System 4.0
510(k) number	K113829
Decision date	April 2nd 2012
Product code	JWH, OOG (21 CFR 888.3560) MBH (21 CFR 888.3565)
Manufacturer	Materialise NV Materialise USA, LLC

Trade or property or model name	*Zimmer®* Patient Specific Instruments System 5.0
510(k) number	K121640
Decision date	December 5th 2012
Product code	JWH, OOG (21 CFR 888.3560)
Manufacturer	Materialise NV Materialise USA, LLC

Device Description

The subject device *Zimmer®* Patient Specific Instruments System 6.0 is a modification to the predicate device *Zimmer®* Patient Specific Instruments System 4.0 (K113829) to accommodate the new compatible implant system *Zimmer® Persona™* components, cleared via 510(k)s K113369, K122745 and K121771. A similar change was done for *Zimmer®* Patient Specific Instruments System 5.0 (K121640) where the *Zimmer® Persona™* components, cleared via 510(k) K113369, were added to MRI image based system. *Zimmer®* Patient Specific Instruments System 6.0 is designed to assist a surgeon in the placement of total knee replacement components for *Zimmer® Persona™* components. The system consists of a software device, branded as *Zimmer®* Patient Specific Instruments Planner (ZPSIP) and a hardware component, branded as *Zimmer®* Patient Specific Instruments (ZPSI).

Intended Use

Total Knee Replacement

The *Zimmer®* Patient Specific Instruments System is intended to be used as a surgical instrument to assist in the positioning of Total Knee Replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The *Zimmer®* Patient Specific Instruments System is to be used with *Zimmer NexGen CR-Flex* fixed bearing, *Zimmer NexGen CR* fixed bearing, *Zimmer NexGen LPS-Flex* fixed bearing, *Zimmer NexGen LPS* fixed bearing, *Zimmer* Gender Solutions Natural – Knee Flex fixed bearing, *Zimmer Persona™* CR fixed bearing, *Zimmer Persona™* PS fixed bearing and *Zimmer Persona™ Trabecular Metal™* prostheses families only.

Unicompartmental Knee Replacement

The *Zimmer®* Patient Specific Instruments System is intended to be used as a surgical instrument to assist in the positioning of Unicompartmental Knee Replacement components intra-operatively and in guiding the marking of bone before cutting and to guide cutting of the bone provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The *Zimmer®* Patient Specific Instruments System is to be used with *Zimmer Unicompartmental High Flex Knee System* prostheses families only.

The *Zimmer®* Patient Specific Instruments are intended for single use only.

Functioning of the Device

The *Zimmer®* Patient Specific Instruments System 6.0 generates a pre-surgical plan based on CT image data sets using the Zimmer Patient Specific Instruments Planner. The software device then is used pre-operatively by a qualified surgeon to inspect, fine-tune and approve the pre-surgical plan. Next, *Zimmer* Patient Specific

Instruments are designed and manufactured based on the approved pre-surgical plan. *Zimmer* Patient Specific Instruments are patient specific templates which transfer the pre-operatively determined positioning of the chosen total knee replacement components to the patient intra-operatively, assisting the surgeon in positioning and aligning the actual total knee replacement components by guiding and marking drill locations.

Technological Characteristics

Device comparison showed that the subject device is substantially equivalent to the Zimmer Patient Specific Instruments System in K113829 and the Zimmer Patient Specific Instruments System in K121640 in terms of intended use, design, functionality, materials, fundamental technology and performance characteristics.

- Both subject device and predicate device are to be used as a surgical instrument to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting.
- The guides of the subject and predicate devices are designed and manufactured from reconstructed three-dimensional models of the patient's anatomy.
- The guides of the subject and predicate devices are made of the same material and follow the same manufacturing process.
- The guide performance of subject and predicate device is guaranteed once the fit of the guide on the patient's anatomy is obtained.
- The software component of the subject and predicate device are intended for use as medical device
- The software component of the subject device is the same software component of the predicate device, only updated with new implants, user interface improvements and minor functional additions.
- The software component of the subject and predicate device functions exactly the same.
- The software component of the subject and predicate device utilized the same programming language and operating system.
- The guides and software of the subject and predicate device have been developed by the same manufacturing company (Materialise NV), based on the same fundamental technology and in-house knowledge
- The guides and software of the subject and predicate device follow the same internal quality procedures and work instructions for design, development, testing and validation.

Performance Data

Results of software verification and validation testing demonstrated the device's safety and effectiveness is substantially equivalent to the predicate device.

Summary

The characteristics that determine the functionality and performance of the subject device, the *Zimmer* Patient Specific Instruments System 6.0, are substantially equivalent to the devices cleared under K113829 and K121640. The *Zimmer* Patient Specific Instrument System will be manufactured in compliance with FDA and ISO quality system requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 22, 2014

Materialise NV
Mr. Oliver Clemens
Quality and Regulatory Officer
Technologielaan 15
3001 Leuven
Belgium

Re: K140027
Trade/Device Name: Zimmer Patient Specific Instruments System 6.0
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH, OOG, OIY
Dated: April 10, 2014
Received: April 14, 2014

Dear Mr. Clemens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140027

Device Name: **Zimmer Patient Specific Instruments System 6.0** (Zimmer Patient Specific Instruments Planner, Zimmer Patient Specific Instruments)

Indications for Use:

Total Knee Replacement

The *Zimmer®* Patient Specific Instruments System is intended to be used as a surgical instrument to assist in the positioning of Total Knee Replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The *Zimmer®* Patient Specific Instruments System is to be used with *Zimmer NexGen CR-Flex* fixed bearing, *Zimmer NexGen CR* fixed bearing, *Zimmer NexGen LPS-Flex* fixed bearing, *Zimmer NexGen LPS* fixed bearing, *Zimmer* Gender Solutions Natural – Knee Flex fixed bearing, *Zimmer Persona™* CR fixed bearing, *Zimmer Persona™* PS fixed bearing and *Zimmer Persona™ Trabecular Metal™* prostheses families only.

Unicompartmental Knee Replacement

The *Zimmer®* Patient Specific Instruments System is intended to be used as a surgical instrument to assist in the positioning of Unicompartmental Knee Replacement components intra-operatively and in guiding the marking of bone before cutting and to guide cutting of the bone provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The *Zimmer®* Patient Specific Instruments System is to be used with *Zimmer Unicompartmental High Flex Knee System* prostheses families only.

The *Zimmer®* Patient Specific Instruments are intended for single use only.

Prescription Use _ X ____ AND/OR Over-The-Counter Use __ _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices